From:	TZOTZOS Katherine -C I O <personal information="" redacted=""></personal>
Sent:	July 16, 2019 1:45 PM
То:	Torrie, Brian (CNSC/CCSN); Consultation (CNSC/CCSN)
Cc:	Jammal, Ramzi (CNSC/CCSN); Elder, Peter (CNSC/CCSN); Viktorov, Alexandre
	(CNSC/CCSN); Riendeau, Nathalie (CNSC/CCSN); Glenn, Karine (CNSC/CCSN); Cameron,
	Jason (CNSC/CCSN); Purvis, Caroline (CNSC/CCSN); VECCHIARELLI Jack -NUCLEAR;
	TRAIN David -NUCLEAR; BOSLEY Mark -NUCLEAR; SCHWARTZ Ephraim -NUCLEAR;
	NGUYEN Loc -NUCLEAR; LO Annette -NUCLEAR; HARRIS Elaine -C I O
Subject:	Notification of OPG Letter: CD# N-CORR-00531-19819 - OPG Comments on Proposed
	Amendments to the Radiation Protection Regulations
Attachments:	N-CORR-00531-19819.pdf; Attachment 1 - Industry comments on Canada Gazette, Part
	I, Volume 153.docx

Dear Mr. Torrie,

Please find attached OPG letter, dated July 16, 2019, from Dr. Jack Vecchiarelli re:

CD# N-CORR-00531-19819 - OPG Comments on Proposed Amendments to the Radiation
Protection Regulations

A word version of Attachment 1 is also attached for your convenience.

Sincerely,

 Katherine Tzotzos

 OSR II
 Business Information Management
 Regulatory Programs, Strategy & Support

 Ontario Power Generation
 (personal information redacted)

 889 Brock Road, Pickering, ON L1W 3J2
 P82 4F3

See how we are powering the future of Ontario at opg.com

THIS MESSAGE IS ONLY INTENDED FOR THE USE OF THE INTENDED RECIPIENT(S) AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, PROPRIETARY AND/OR

CONFIDENTIAL. If you are not the intended recipient, you are hereby notified that any review, retransmission, dissemination, distribution, copying, conversion to hard copy or other use of this communication is strictly prohibited. If you are not the intended recipient and have received this message in error, please notify me by return e-mail and delete this message from your system. Ontario Power Generation Inc.



Jack Vecchiarelli Vice President

Nuclear Regulatory Affairs and Stakeholder Relations

889 Brock Road Pickering, Ontario L1W 3J2

personal information redacted

OPG Proprietary

July 16, 2019

CD# N-CORR-00531-19819

MR. BRIAN TORRIE Director General, Regulatory Policy Directorate Canadian Nuclear Safety Commission 280 Slater Street Ottawa, ON K1P 5S9

Dear Mr. Torrie:

OPG Comments on Proposed Amendments to the Radiation Protection Regulations

The purpose of this letter is to provide Ontario Power Generation (OPG) comments on the proposed amendments to the *Radiation Protection Regulations* as published in *Canada Gazette*, Part I, Volume 153, dated June 15, 2019.

Specifically, OPG requests the proposed lens of an eye equivalent dose rate of 100 mSv for a five-year dosimetry period be removed from the amended Regulations. While OPG supports reducing the annual limit from 150 to 50 mSv, there is no scientific consensus for the proposed five-year limit, which rather than enhance worker safety could unintentionally restrict the ability of critical skilled tradespeople to perform radioactive work. Given this, OPG encourages the CNSC to convene a workshop with industry and impacted workers before the amended Regulations are finalized. This will ensure a common understanding of the proposed changes, their scientific rationale and long-term impacts.

With respect to the proposed lens of the eye dose limits, OPG notes:

- 1. there is no dosimetry method capable of accurately measuring dose to the lens of the eye in mixed beta and gamma radiation fields;
- 2. vendors, unions, and impacted tradespeople have not yet been consulted;
- 3. there is no clear scientific consensus on a threshold for cataract formation;
- 4. the cost of compliance has been greatly underestimated; and,
- 5. the new limits are not appropriate for Canadian nuclear power technology and workplaces.

In the absence of accurate dosimetry for lens of the eye in beta radiation fields, surrogate measurements will be used to provide a conservative estimate of dose. Surrogate measurements may result in dose estimates that are five to six times greater than the actual lens dose. The dose estimates will need to be further verified through field study and corrected for the shielding effect of personal protective equipment. The application of surrogate measurements to large groups of workers will compound the need for corrections.

These conservative, surrogate dose measurements will result in the premature removal of personnel from work. Boilermakers and other skilled trades workers will receive conservative dose estimates from each nuclear power plant operator. Additionally, foreign workers may not have access to their radiation data history, know whether and/or how their lens of the eye dose was determined, or have a different set of regulatory limits (e.g. United States) that would prevent them from being recruited to work in Canada.

© Ontario Power Generation Inc., 2019. This document has been produced and distributed for Ontario Power Generation Inc. purposes only. No part of this document may be reproduced, published, converted, or stored in any data retrieval system, or transmitted in any form by any means (electronic, mechanical, photocopying, recording, or otherwise) without the prior written permission of Ontario Power Generation Inc.

The vendors and unions that have personnel working at multiple licensed sites were not consulted on the proposed amendments and are largely unaware of the impact of the conservative measures that will be required to comply with the proposed amendments. The conservative dose estimates and associated work removals will require vendors to hire and train additional staff, or to rotate staff, to ensure compliance with the new lens dose limits.

The industry also continues to be uncertain regarding the claim of a low threshold for radiationinduced cataract formation, given the inability of researchers to establish a link between medical radiation exposure and cataract surgery, which effectively rules out a dose response effect. In 2018, a team of Canadian radiation experts released its review of all published human epidemiological data on ionizing radiation exposure to the lens of the eye, including data from atomic bomb survivors, Chernobyl liquidators, medical workers and radiotherapy patients (Reference 1). It found "there is not conclusive evidence that the threshold dose for cataract formation should be reduced" to the International Commission on Radiological Protection level that forms the basis of the CNSC's proposed amendments.

The lack of scientific certainty was also noted by the United States Nuclear Regulatory Commission (NRC), which chose to discontinue rulemaking in this area as proposed lens dose limits would have no clear safety benefit. In its 2016 decision (Reference 2), the NRC determined its "*regulatory framework continues to provide adequate protection of the health and safety of workers, the public, and the environment*" and "*NRC staff believes that there is minimal adverse impact on the NRC's mission, principles, or values by discontinuing this rulemaking.*"

The reduced dose limit will result in significant additional cost and administrative burden to demonstrate that workers are below the proposed five-year regulatory lens of the eye dose limit. These estimates are significantly greater than the CNSC estimate of \$141,240 annually to the whole industry, as stated in the Regulatory Impact Analysis Statement.

Worker safety is OPG's top priority. OPG maintains that the CNSC should follow the US NRC in taking a decision to discontinue rulemaking in this area. OPG supports the reduction of the annual lens of the eye dose limit from 150 mSv (15 rem) to 50 mSv (5 rem), and elimination of the proposed restrictive lens five-year dose limit of 100 mSv (10 rem).

Additional feedback on all of the proposed changes to the *Radiation Protection Regulations* is provided in Attachment 1, which details comments and requests for clarification that emerged from a collaborative review of the proposed Regulations with industry peers.

If you have any questions, please contact me at (905) 839-6746, extension 5444, or at jack.vecchiarelli@opg.com.

Sincerely,

√Jack Vecchiarelli Vice President Nuclear Regulatory Affairs & Stakeholder Relations Ontario Power Generation Inc.

Attach.

cc: R. Jammal - CNSC (Ottawa) P. Elder - CNSC (Ottawa) J. Cameron - CNSC (Ottawa) A. Viktorov - CNSC (Ottawa) N. Riendeau - CNSC (Ottawa) K. Glenn - CNSC (Ottawa)

References:

- 1. Christopher Thome, Douglas B. Chambers, Antony M. Hooker, Jeroen W. Thompson, "Deterministic effects to the lens of the eye following ionizing radiation exposure: Is there evidence to support a reduction in threshold dose?", Health Physics Society, 2018.
- 2. U.S. Federal Register, Vol. 81, No. 249, III. Radiation Protection (RIN 3150–AJ29; NRC–2009–0279).

ATTACHMENT 1

Industry comments on Canada Gazette, Part I, Volume 153, Number 24: Regulations Amending Certain Regulations Made under the Nuclear Safety and Control Act (Radiation Protection)

#	Document/ Excerpt of Section	Industry issue	Suggested Change (<i>if applicable</i>)	Major Comment/ Request for Clarification	Impact on Industry, if major comment
1.	RIAS, Section 13	Contrary to the RIAS, the details of how radon progeny are to be calculated in effective dose are not in the current draft of <i>REGDOC-2.7.2, Dosimetry: Ascertaining</i> <i>Occupational Dose.</i> This is a significant omission for licensees of uranium mines and mills. Please see related comments 12 and 13.	The regulations should detail the method for how radon progeny is included in the effective dose calculation for uranium mines and mills; specifically, the dose conversion factor between WLM and mSv.	MAJOR	For licensees of uranium mines and mills, the removal of how radon progeny is calculated from the regulations (and REGDOC) means there is no clear review and consultation process for any proposed changes to the dose conversion factor from exposure (WLM) to dose (mSv). How radon progeny is included in the effective dose calculation is fundamental to the determination of whether the dose limits are being met. As a result, there is a need for clarity on both the actual calculation and the process or changes. Since there is no cost identified with this change, it is assumed the CNSC intends to continue to accept the current conversion factor of 5 mSv/WLM. However, this is not documented in the current draft of <i>REGDOC-2.7.2.</i> If a change to the radon progeny dose conversion factor is proposed in the future, it should undergo a Regulatory Impact Analysis equivalent to that done for regulations. The CNSC committed to a technical review and consultation specific to a change to the dose calculation for radon progeny in <i>DIS-13-01</i> <i>Proposal to Amend the Radiation Protection Regulations</i> (pg. 12).
2.	RIAS, Section 14, para. 1	In 2016, the United States Nuclear Regulatory Commission decided not to proceed with rulemaking in this area because it would result in little, <u>if any</u> , improvement in occupational or public safety. (Please see U.S. Federal Register /Vol. 81, No. 249). In fact, recent scientific research suggests it is not possible to establish a link between radiation exposure and cataract production. These findings call into question whether there is an identifiable threshold for cataract formation.	Amend to read, "Radiation exposure to the lens of the eye, above a threshold dose, has been linked to its opacification (or clouding of the lens, which in its advanced stages, is referred to as a cataract). <u>Data has shown that personnel involved in industrial radiography and medical diagnostic and interventional radiology have a higher risk."</u>	MAJOR	Even if the scientific research supported a measureable linkage between dose and cataract formation, Nuclear Energy Workers at most nuclear facilities are largely unaffected by this type of exposure. The CNSC should clarify there are workers in the medical and NDE fields who may not be sufficiently protected and it is these individuals they are targeting with the amendments.

Industry comments on Canada Gazette, Part I, Volume 153, Number 24 Regulations Amending Certain Regulations Made under the Nuclear Safety and Control Act (Radiation Protection)

#	Document/ Excerpt of Section	Industry issue	Suggested Change (<i>if applicable</i>)	Major Comment/ Request for Clarification	Impact on Industry, if major comment
3.	RIAS, Section 14 para. 3, bullet 2	Industry has significant concerns with the proposed introduction of a 5-year limit in the section on equivalent dose limits for the lens of an eye. If passed, this new limit would introduce significant operational challenges to licensees with no improved safety benefit to workers. Specially, the 1 st bullet in Section 14 sets a target of no single year exceeding 50 mSv. However, the second bullet sets a 5-year limit of 100 mSv, which is effectively a 20 mSv limit for any given year.	Delete the second bullet and recognize that licensees should be expected to minimize dose to the lens of the eye through their ALARA (as low as reasonably achievable) programs.	MAJOR	The proposed 5-year limit creates a significant administrative burden only to demonstrate that Nuclear Energy Workers are sufficiently protected from a threshold of questionable validity. Also, there could be an impact on the livelihood of tradespeople who will be subject to dose estimates based on overly-conservative surrogate measurements. Boilermakers and other tradespeople who work at multiple licensed sites will receive overly-conservative dose estimates at each of the sites. This will cause them to prematurely approach the permissible dose limits and impact their availability to do radioactive work. Canada already faces an undersupply of talented tradespeople and an overly-conservative 5- year limit will only exacerbate that issue with no corresponding benefit to worker safety. While industry believes it can adapt to the proposed reduction in the current limit from 150 mSv to 50 mSv in a one-year dosimetry period, the 5-year limit does not enhance safety commensurate with its associated challenges and, therefore, is inconsistent with industry's ALARA principles.
4.	RIAS, Regulatory Development, para. 4	Industry concerns went beyond the administrative and financial burden. They questioned the science behind the threshold and limit and the absence of a methodology for measuring lens of the eye dose in mixed radiation fields. Licensees suggest the CNSC conduct an epidemiological or health effects study on Canadian nuclear energy workers regarding radiation-induced lens of the eye opacification/cataracts.	Amend to read, "However, they questioned the benefit of some of the proposed changes given the potential administrative and financial burden. <u>They also specifically</u> <u>challenged the scientific credibility of</u> <u>the linkage between a lens of the eye</u> <u>dose threshold and cataract</u> <u>formation."</u>	MAJOR	Worker safety is industry's top priority. As written, this falsely implies that licensees were only concerned with financial impacts. As per comment #3, Canadian industry already faces an undersupply of talented tradespeople and an overly-conservative 5- year limit will only exacerbate that issue with no corresponding benefit to worker safety.

#	Document/ Excerpt of Section	Industry issue	Suggested Change (<i>if applicable</i>)	Major Comment/ Request for Clarification	Impact on Industry, if major comment
5.	RIAS, Regulatory Development, Section 14, bullet 3	The text suggests that stakeholders are comfortable with workers receiving health effects such as cataracts. Stakeholders were, in fact, opposed to treating, or suggesting that cataracts be treated, as equivalent to cancer-related dose effects.	Amend to read, "claiming that the change in the dose limit is not warranted, considering that the health effects (cataracts) are regarded as easily treatable;"	MAJOR	Worker safety is industry's top priority. As written, this falsely implies that licensees are comfortable with workers receiving health effects such as cataracts.
6.	RIAS, re. Regulatory Development, Section 14 bullet 4	The 4 th bullet is incomplete and contextually inaccurate as currently written.	Amend to read, " citing significant financial and administrative burden with the proposed change and the associated impact on their operation, in particular for those exposure situations with non-uniform fields where the lens of an eye dose could be the limiting exposure for workers <u>because of the need to</u> <u>conservatively estimate rather than</u> <u>measure the exposure.</u> "	MAJOR	Worker safety is industry's top priority. As written, this falsely implies that licensees were only concerned with financial impacts.
7.	RIAS, Regulatory Development, Section 14, 2 nd para., last sentence	As per comment #1, the US NRC rendered a decision not to proceed with rulemaking in this area, because of the <u>lack of a clear</u> <u>safety benefit</u> .	Delete the final sentence, "However, it is clear that lens opacities and resulting radiation-induced cataracts are a health effect that can and should be prevented."	MAJOR	This is a misrepresentation. The results are inconclusive and subject to challenge and that should be reflected here.

#	Document/ Excerpt of	Industry issue	Suggested Change (<i>if applicable</i>)	Major Comment/	Impact on Industry, if major comment
	Section			Request for	
	Section			Clarification	
8.	RIAS,	No rational is provided for distinguishing	For clarity, remove the term "skins of	MAJOR	It would still not be clear to industry how to apply the equivalent
	Regulatory	between the skin as a whole, and the skin of	the hands and feet" for the following		limit to the hands and feet.
	Development,	the hands and feet. The proposed change to	reasons:		
	Sections 8 and	"skin of the hands and feet" could add more	1) the ICRP has never defined what		
	14	confusion than clarity. Section 14(3) states	"hands and feet" mean		
		that "when the skin is unevenly irradiated,	2) the limits for "skin" and "skin of		
		the equivalent dose received by the skin is	the hands and feet" are the same		
		the average equivalent dose over the 1 cm ²	3) it would close any distinctions that		
		area that received the highest equivalent	might allow a single location of the		
		dose." Therefore, all dose received by the	skin to receive up to 1 Sv of dose		
		"skin of hands and feet" must be included in	merely because it occurs on a hand		
		skin dose, because the skin is unevenly	or foot		
		irradiated.			

#	Document/ Excerpt of Section	Industry issue	Suggested Change (<i>if applicable</i>)	Major Comment/ Request for Clarification	Impact on Industry, if major comment
9.	RIAS, Section 20,	Industry has significant concerns with the section on labelling and believes a workshop with CNSC staff is necessary to ensure common understanding. Licensees agree containers and devices containing nuclear substances should be labelled to alert persons to the presence of a nuclear substance and the real or potential hazard/risk that exists. However, NEWs are trained to recognize hazard levels and understand the risks when reading posted radiation fields (e.g. mrem/h, mSv/h, MPCa or DAC, cpm, etc.) Given this, listing radionuclides and associated activities on waste containers intended to stay within a nuclear facility does not improve the safety for personnel. Licensees agree that containers/sources shipped out of the facility should have the appropriate specifics. Also, the exemption cited in this section does not apply to containers and devices in a designated posted area which imposes measurement requirements that are unnecessary.	 Industry requests the CNSC host a workshop to ensure the requirements are clearly understood and key terms defined. Items for discussion could include: Defining 'container' and 'device'. Does it mean radiation device per NSRD regulations? Applying the exemption to the labelling requirements for containers or devices in an area subject to the boundary and point of access signs in s. 21. 	MAJOR	For containers intended to be used only within the licensee's facility, like those for waste, adding specifics on radionuclides inadvertently creates a safety risk when staff are trained to evaluate risk based on hazard conditions (dose rates or air concentrations). Waste cans are frequently emptied by trained and qualified staff. There is also an administrative burden that would require each bag or container to be sampled, analyzed, tags printed and affixed to the item. Also, clear regulations promote better compliance. The absence of definitions can lead to licensees' interpretations which may not meet the intent of the regulation's requirements.

#	Document/ Excerpt of Section	Industry issue	Suggested Change (<i>if applicable</i>)	Major Comment/ Request for Clarification	Impact on Industry, if major comment
10.	RIAS, Table 1	The analysis does not account for the additional staff that will need to be hired, on-boarded, trained, etc. to take the place of those staff that prematurely approach their permissible dose limits. Also, no formal request has been made for cost information. An informal request was responded to in December 2018, but there has been no follow-up discussion.	As per comment #9, industry requests the CNSC workshop include a review of its cost model and the discrepancies between the RIAS and the impacts provided by industry.	MAJOR	Incomplete / inaccurate cost information. Changes to resourcing needs would be significant with no corresponding benefit to nuclear safety. Some licensees estimate the changes could cost an additional \$6-12 million for maintenance and major component replacement outages. Other licensees estimate up to \$500,000 will be required initially - and \$250,000 annually - to amend work practices/procedures to comply with the proposed limits.
11.	One-for-One Rule	Industry disputes the statement, "The CNSC does not expect the proposed Regulations to increase the administrative burden of licensees or applicants. Therefore the One- for-One rule does not apply to the proposed Regulations."	Delete this statement.	MAJOR	Operating experience confirms that changes of this type have significant impacts on administrative burden as per comment #10.
12.	1, 5(1), 5(2), 19(f)	The definitions of radon and radon progeny should apply to exposures occurring as a direct result of a CNSC-licensed activity, such as exposures to radon and radon progeny in uranium mining and milling, as stated in REGDOC 2.7.1	Amend the document to clarify that it applies to exposures occurring as a direct result of a CNSC-licensed activities (e.g. uranium mines and mills) only and that radon and radon progeny from natural sources do not need to be included in effective dose calculations.	MAJOR	Without clarity, the inclusion of radon and its progeny could lead some to misinterpret that dose from naturally occurring radon progeny must be ascertained. The concept of effective dose sufficiently captures the whole-body dose from all sources of radiation resulting from licensed activities.
13.	1(1)	Contrary to what is stated in the RIAS, the definitions of <i>working level</i> and <i>working level month</i> have not been included in the current draft of <i>REGDOC-2.7.2</i> to support the calculation of effective dose.	This term should be defined for uranium mines and mills only throughout the document.	MAJOR	Uncertainty and inconsistency.

#	Document/ Excerpt of Section	Industry issue	Suggested Change (<i>if applicable</i>)	Major Comment/ Request for Clarification	Impact on Industry, if major comment
14.	7 (1) (d) and 10	Bullet (d) of Section 7 (1) changes the requirement to provide a "worker's radiation dose levels" to the "worker's radiation dose levels received on an annual basis." Licensees may not be able to collect workers' personal addresses or other contact information.	Add a bullet to Section 10 on NEW obligations that says, <u>"(f) the</u> <u>worker's current mailing and/or</u> <u>email address</u> "	MAJOR	Industry needs supporting regulations to require NEWs to provide a current mailing/email addresses so licensees can meet this obligation.
15.	7 (1) (e)	The requirement to inform all NEWs of their duties and responsibilities during an emergency may not be realistic depending on the level of detail expected. Emergencies, by their very nature, are not always predictable and it may not be possible to accurately foresee the emergent conditions.	Amend the requirement to specify providing a general description of expected responsibilities during emergency scenarios and include an explanation of risks with doses up to the emergency dose limits without explaining specific responsibilities.	MAJOR	Depending on the level of detail expected, this may be impossible with several thousand nuclear energy workers on some sites at any given time. Without clarity, this could unintentionally create instant and widespread non-compliance.
16.	7 and 11	Industry supports the repeal of the provision for a female NEW to self-disclose her pregnancy to the licensee as long as the regulations are clear with regard to licensees' obligations. This proposal aligns with the international practice of voluntary self-disclosure of pregnancy and nursing.	Amend the regulations to clarify that the responsibility lies with the pregnant or nursing NEW to declare their status to the licensee in writing. Until such a declaration is provided, the licensee has no obligation to accommodate work assignment or dose limits associated with pregnant or nursing status.	MAJOR	Without this, it is difficult for licensees to comply with the requirement to ensure that pregnant workers are not used in the control of an emergency. Also, the risks and rights may have been given to the female NEW many years prior to becoming pregnant. Declaring pregnancy to the licensees affords an opportunity to provide her with the most current information and refresh her on the risks.

#	Document/ Excerpt of Section	Industry issue	Suggested Change (<i>if applicable</i>)	Major Comment/ Request for Clarification	Impact on Industry, if major comment
17.	8, 10 and 18	For the purposes of epidemiological studies using the National Dose Registry (NDR) data, "sex" (i.e. male/female) is the relevant quantity of interest, not "gender." It is unknown whether NDR will be updated to accept data for genders. If this change is made, the acceptable/expected genders should be defined and changes to NDR submission requirements communicated to licensees in advance.	Maintain "sex" as the descriptor.	MAJOR	At this time, adopting the term "gender" increases uncertainty since the change is inconsistent with reporting under the NDR.
18.	11 (1) and (2)	The requirement to accommodate workers as described is already covered by existing provincial and federal laws.	Remove the redundant requirements related to accommodations.	Clarification	
19.	11 (2)	As currently written, the regulations do not indicate whether a pregnant NEW can revoke her declaration of pregnancy.	Amend Section 11 to include the following: <u>"A female nuclear energy</u> worker may revoke, at any time, her written declaration that she is pregnant. Upon receipt of this revocation, the licensee must proceed as if it had never been informed of the pregnancy or breastfeeding."	MAJOR	Other jurisdictions allow pregnant NEWs to revoke their declaration. With the addition of the ability to voluntarily declare, it gives a female NEW a new method to cope with the psychological pain of spontaneous or induced abortion by simply revoking the declaration instead of informing the licensee of the fate of the foetus.

#	Document/ Excerpt of Section	Industry issue	Suggested Change (<i>if applicable</i>)	Major Comment/ Request for Clarification	Impact on Industry, if major comment
20.	14	The proposed new dose limits for the lens of an eye will be identical as the WB effective dose limits. Industry supports the reduction of the annual dose limit from 150 mSv (15 rem) to 50 mSv (5 rem), but opposes the proposed 100 mSv over a 5-year dosimetry period. Implementation of the 5-year dose limit is not feasible with currently available technology, particularly in mixed beta/gamma fields. There is no dosimetry method reasonably accessible to licensees capable of accurately measuring dose to the lens of the eye in mixed beta and gamma radiation fields. Eye lens dosimeters tend to be overly responsive to beta. Also, surrogate measurements are overly conservative. Surrogate measurements and devices developed for use in hospitals and laboratories are not appropriate for industrial settings. They have been shown to lack the durability required and the potential for contamination of these types of dosimeters makes them highly impractical for a number of licensees.	Retain the 5 rem (50 mSv) per year equivalent dose, but remove the proposed 10 rem (100 mSv) over 5 years.	MAJOR	There is no scientific consensus for the proposed 5-year equivalent dose of 100 mSv (10 rem), which current research shows is not required. As per comment #3, the proposed 5-year dose would introduce operational complexities and administrative challenges to demonstrate that workers are below regulatory dose limits. In the absence of accurate dosimetry for lens of the eye in beta radiation fields, surrogate measurements would be used to provide a conservative estimate of dose. In turn, these conservative estimates would lead to the premature removal of workers from performing radioactive work.
21.	14	The proposed changes to the table to subsection 13 (1), Item 1 Column 1, does not convey that a pregnant NEW can revoke her pregnancy declaration.	This is not an issue if the suggested change for Section 11 is incorporated	MAJOR	A licensee would be forced, by the letter of the regulations, to maintain the special dose limit for a pregnant NEW unless the pregnant NEW has the ability to revoke her declaration.

#	Document/ Excerpt of Section	Industry issue	Suggested Change (<i>if applicable</i>)	Major Comment/ Request for Clarification	Impact on Industry, if major comment
22.	14	In the table to subsection 13 (1), the proposed dose limits allow for a lower dose limit for a child of a breastfeeding worker (1 mSv) (i.e. Person who is not a nuclear energy worker) than a foetus (4 mSv), when the foetus is more radiosensitive.	Amend to include the following note, "Subsection (1) does not apply in respect of a child of a breastfeeding NEW."	MAJOR	Without clarity, for I-131 for example, this would cause a disparity where a pregnant NEW could receive 4 mSv effective dose and her foetus would receive 11 mSv CED. But the same NEW with the now child, born on January 1 st , would be limited to receiving 0.38 mSv effective dose per year because her child would be limited to 1 mSv CED (assuming I-131).
23.	15	The proposed change to subsection 14(1) provides no definition of equivalent doses. Having one is important in the context of the dose limit regarding the lens of the eye.	Define equivalent doses in Section 14 (1) (i.e. the equivalent dose for the lens of the eye is Hp(3), or accepted alternative).	MAJOR	Without a definition, particularly in mixed radiation fields, there is uncertainty around measurements of true Hp(3) doses and potential for significant overestimation. In addition, a definition would require dosimetry providers to show how estimation algorithms estimate the Hp(3) dose, as opposed to what they would consider an "eye dose".
24.	15	While there are no proposed changes to Section 15, Emergencies, licensees believe there is an opportunity to add clarity to this section while the regulations are being amended. Please see the requested change in the next column, which is an expectation/interpretation mentioned in other regulatory documents (<i>REGDOC</i> 2.10.1, Emergency Management and Fire Protection, Volume II and REGDOC 2.7.1, Radiation Protection). Reinforcing this in the RPRs would create additional clarity.	Include a statement in Section 15 of the amended regulations to read: "Dose received from emergency response activities should be treated separately from regular occupational doses."	Clarification	
25.	15	Regarding the table for Section 15 of the regulations, given that the equivalent dose limits for items 2 and 3 are the same, and they both refer to skin equivalent doses, it is not obvious why they need to be differentiated.	If the separate listing of dose limits for items 2 and 3 is meant to force different reporting and dosimetry requirements, that should be clarified somewhere in the RPR, potentially in Section 5.	Clarification	

#	Document/ Excerpt of Section	Industry issue	Suggested Change (<i>if applicable</i>)	Major Comment/ Request for Clarification	Impact on Industry, if major comment
26.	18	The definition of "management system" cannot be found in the regulations. Also, industry has no issue with the replacing paragraphs 18 (b) and (c) in the regulations as long as the changes in terminology do not introduce new requirements.	Include a definition for "management system" and confirm the terminology changes in 18 (b) and (c) carry no new requirements.	Clarification	
27.	20	Licensees have concerns with proposed changes to Section 21. For licensees with facilities designed for the purpose of processing large volumes of radioactive material, e.g. uranium mills, there is little benefit to putting signage on every entrance to those facilities indicating that the radioactive material is present.	Add a subsection to exempt the application of s. 21(1) to facilities whose purpose is the bulk processing and handling of radioactive materials. Also, licensees request the rationale behind the change to posting to vehicles in Section 21. Industry believes this better covered by a REGDOC.	MAJOR	Maintenance of a significant number of signs creates an administrative burden with no corresponding safety benefit. Operating experience shows too many signs can actually create confusion, not clarity.
28.	22	Industry has significant concerns that Section 24.1 is overly broad as currently written. This concern also relates to RIAS Section 22: <i>Proposed new section on</i> <i>radiation detection and measurement</i> <i>instrumentation</i> .	Industry believes the subtleties of language are very important in this area and propose this be discussed as part of the workshop proposed in comment #9. Specifically, licensees urge the CNSC to amend 24.1 to read, "Every licensee must ensure that instruments and equipment that are used for radiation measurements <u>related to direct, personnel</u> <u>protection</u> are selected, tested and calibrated for their intended use."	MAJOR	"Radiation measurements" include in-core flux detectors and other detectors related to radiation processes not related to radiation protection. As written, it would be illegal to have a licenced fixed gauge out of calibration because it would not be "calibrated for" its intended use (because it 'measures radiation'), having nothing to do with Radiation Protection.

#	Document/ Excerpt of Section	Industry issue	Suggested Change (<i>if applicable</i>)	Major Comment/ Request for Clarification	Impact on Industry, if major comment
29.	25	Compliance for using new dose factors (0.12 and 0.88) should align with the effective implementation for new eye dose limits which is Jan 1, 2021.	Revise to align with the new lens of the eye dose limits.	MAJOR	Without adequate time for implementation, industry could be in non-compliance with the new regulations upon their publication.
30.	25	Compliance with s. 15(2) within the proposed transition period is not possible. Industry notes that in Europe, this took five years to implement.	Section 15(2) should not come into effect until January 1, 2024 to allow for dosimetry services for mixed radiation fields to become available for monitoring of Hp(3). This is consistent with the implementation period in Europe.	MAJOR	This is currently an evolving field, and there are no certified dosimetry services in North America that provide Hp(3) for mixed radiation fields.
31.	Part 3	Industry has concerns with a subjective concept such as ALARA (as low as reasonably achievable) being explicitly tied to administrative monetary penalties as they are in Items 2-5 in Part 3.	Remove the phrase "as low as reasonably achievable" from Items 2, 3, 4, 5.	MAJOR	It is inappropriate to link a subjective concept with a monetary penalty.
32.	Part 3	Industry has concerns with Item 34, provision 15(7), "Requesting a pregnant woman to participate in the control of an emergency"	Amend to read "Requesting a <u>NEW</u> who has declared pregnancy to participate in the control of an emergency."	MAJOR	Unless a pregnant woman was required to declare pregnancy, it is possible that a licensee could unknowingly request a pregnant woman participate in the control of an emergency.
33.	Schedules 1 and 2	Changing the tissue weighting factors and the radiation weighting factors to match ICRP 103 recommendations would invalidate all previous dose conversion coefficients. The ICRP has yet to release all dose coefficients based on the 2007 recommendations.	Retain the weighting factors from the ICRP 60 recommendations until all current dose coefficients are updated to the new recommendations. The other option would be to treat either set of weighting factors as equally valid.	MAJOR	Industry would have to self-fund the development of dose conversion coefficients for all radionuclides and situations, something the international community of Health Physicists has yet to do. This cost is not considered in the regulatory impact statement.
34.	Schedule 2	It is assumed that a spelling error is present in item 3 of schedule 2, and such the correct reading is "Protons and charged pions."	Change the first instance of "neutrons" to "protons" as per ICRP 103.	MAJOR	Without a change, the regulations would not provide a radiation weighting factor for protons.

#	Document/	Industry issue	Suggested Change (if applicable)	Major	Impact on Industry, if major comment
	Excerpt of			Comment/	
	Section			Request for	
				Clarification	
35.	Schedule 2	Column 1 specifies "all energies" for some	Remove "energy range" and "all	MAJOR	Leaving the table as proposed would make items 3 through 5
		types of radiation so that "energy range"	energies" as they are redundant. See		technically in error because column 1 does not denote an energy
		does not appear necessary.	ICRP 103.		range.
36.	Schedule 2	As currently written, the industry could	Reference the continuous function of	MAJOR	Industry would not be able to follow the same standard without this
		lawfully use any "continuous function of	neutron weighting factor from ICRP		clarification.
		neutron energy" as a weighting factor.	103. The alternatives would be to		
			provide a graph like schedule 3 of the		
			RPR or include the equations directly		
			to reconstruct the function.		